

## **Selected questions and answers on bisphenol A in feeding bottles and dummies for babies**

Updated FAQs, 2. October 2009

Many plastic products, including baby bottles contain the chemical substance bisphenol A (BPA). Numerous scientific studies on the international level have examined the effects of this substance on human health. Some of the results are contradictory. At regular intervals the media take up the topic of bisphenol A in baby bottles and examine whether the substance presents a risk to infants. Anxious parents ask themselves whether they should switch to a different type of baby bottle. There are currently reports in the media about bisphenol A in baby dummies. They were prompted by analytical findings from environmental associations in Germany and Austria. Here BfR answers the most frequently asked questions about bisphenol A.

### **What is bisphenol A?**

Bisphenol A is the industrial chemical 2,2-bis(4-hydroxyphenyl)-propane. It is used as a starting material for the production of polycarbonate plastics and synthetic resins.

### **Where is bisphenol A found?**

The substance may be found in plastic objects as well as articles that come into contact with food. Examples are baby bottles, drinking beakers, plastic tableware and the inner coating of cans.

### **What is the effect of bisphenol A?**

The substance has low acute toxicity. There are no indications of any carcinogenic effects. However, bisphenol A does belong to a group of substances with hormone-like (oestrogen) action. These substances are described scientifically as “endocrine disruptors”. In the human body bisphenol A is rapidly converted into a metabolite that no longer has any oestrogenic activity and is eliminated via the kidneys. More recent findings indicate that this constitutes a major difference to rodents which present slower elimination of bisphenol A in experimental studies.

A number of recent studies on laboratory animals look at the possible harmful effects of even the smallest amounts of bisphenol A and in particular its oestrogenic action. Some of these studies are difficult to interpret and some are even contradictory. This was the reason for a new long-term study in mice over a large dose range. Based on the data from this study, the health risk of bisphenol A was reassessed on the European level and a safe limit value was established. BfR experts were involved in this evaluation.

### **Do infants ingest harmful amounts of bisphenol A from baby bottles?**

A TDI value has been established down for bisphenol A on the European level. This value quantifies the amount that a person can ingest daily over his entire lifetime (tolerable daily intake) without it having any harmful effects on his health.

The TDI value for bisphenol A is 0.05 milligram per kilogram bodyweight (i.e. 3 mg for a person weighing 60 kg). It includes a safety factor of 100. In order to ensure that this value is not exceeded, products containing bisphenol A may only release certain amounts of this substance.

This also applies to baby bottles made of polycarbonate. The amount of bisphenol A that can be released into the baby food has to be small enough for any bisphenol A ingested by the baby to remain safely below the TDI value. This is the case for bottles that are commercially available in conjunction with normal use. Official food control could not detect any bisphenol A during spot checks on the contents of baby bottles that were heated under normal domestic conditions. Hence there is no health risk for babies fed from bottles made of polycarbonate. BfR, therefore, believes that there is no need to forego using polycarbonate bottles.

#### **Are there alternatives to baby bottles made of bisphenol A?**

Based on the latest scientific findings BfR believes that there is no need to stop using baby bottles made of polycarbonate. However, parents who are still uncertain have the option of changing to glass bottles. However, it should be borne in mind that glass bottles can break. Bottles made of polyether sulphone are also available for purchase and are advertised as “BPA-free”. However, this substance has been less scientifically investigated than bisphenol A.

#### **Why has bisphenol A not been banned?**

Following careful examination of all studies, in particular the studies in the low dose range of bisphenol A, BfR comes to the conclusion in its scientific assessment that the normal use of polycarbonate bottles does not lead to a health risk from bisphenol A for infants and small children. BfR is not alone in this assessment. The European Food Safety Authority (EFSA) and the U.S. Food and Drugs Administration (FDA) share this opinion. Japan, which has conducted its own studies on the bisphenol A problem, does not see any need for a ban either. For the migration of bisphenol A from polycarbonate there is a statutory binding limit value. It is 0.6 milligram per kilogram food. This means that if an adult weighing 60 kg eats a kilogram of food with a bisphenol A content of 0.6 mg, he uses up one-fifth of his TDI value of 3 milligram per day.

When BfR receives information about health risks for consumers, the Institute informs the public authorities named by the legislator for regulatory purposes and, of course, the public at large. Hence BfR is not in a position to issue a ban on the use of bisphenol A for two reasons. Firstly, the use of the substance is regulated on the European level. Secondly, BfR has the statutory remit of assessing risks and disseminating management options for their reduction.

#### **Why is bisphenol A in baby bottles currently being discussed?**

Environmental associations in Germany and Austria have examined baby dummies for bisphenol A. The results of the laboratory point to unexpectedly high levels of bisphenol A both in the protective plastic coatings and in the teats of dummies. No data are currently available on the amount of bisphenol A that migrates from the dummies when in use.

#### **How is it that the teat parts of dummies may possibly contain bisphenol A?**

At the present time, we do not know how bisphenol A can reach the teat part of the dummy. The substance is used as a starting material for the production of polycarbonate plastic. The teats, however, are made of latex or silicone. No bisphenol A is required for the production of these materials. A migration of substances from the protective plastic coating of a dummy to the teat is unlikely based on the knowledge available so far under normal conditions of use.

#### **What is BfR currently doing in response to the study findings on bisphenol A in baby dummies?**

BfR takes the results of the environmental associations very seriously. Hence there is an urgent need for an analytical review of the findings by other laboratories. BfR is also conduct-

ing its own tests. The decisive factor for comprehensive risk assessment is how much bisphenol A could migrate during use of the dummies. BfR will, therefore, seek to obtain data above all on the migration of bisphenol A from dummies. Further studies are necessary in order to identify the migration sources.

**Which dummies may contain bisphenol A?**

According to the data of the analytical laboratory bisphenol A may be contained in both latex and silicone dummies, but this requires confirmation.

**Is there a health risk for children who use dummies over a longer period?**

There is no acute health risk from the uptake of bisphenol A. The substance is ingested in daily life from many sources, for instance from water bottles or microwave containers. The first step must be to measure release rates in order to ascertain whether dummies are a further source of intake.